

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)

No. MDL 1:13-md-02419

This Document Relates To:)
)

MOTION FOR PROTECTIVE ORDER FOR MICHAEL O'NEAL

Michael O'Neal moves the Court for Protective Order pursuant to Fed. R. Civ. P. 26(c)(1) and Fed.R. Civ. P. 45(c)(3). O'Neal was served with a subpoena duces tecum by the Plaintiffs' Steering Committee. The grounds for this motion are: (1) most materials subject of the subpoena duces tecum are privileged and are not discoverable under the Tennessee Patient Safety and Quality Improvement Act ("TPSQIA"); (2) recognition by this Court of a medical peer review privilege for the materials subject of the subpoena duces tecum is consistent with the public policy evident in the TPSQIA, the intent behind the Patient Safety Quality Improvement Act of 2005 ("PSQIA"), and the particular circumstances of this case; (3) discovery of the materials subject of the subpoena duces tecum, if allowed by this Court, will render ineffective the ruling of the Tennessee court which barred discovery of O'Neal's reports and communications related to his pharmacy consulting for St. Thomas Outpatient Neurological Center, LLC; and (4) the subpoena at issue is overly broad, and, therefore, unduly burdensome on O'Neal.

In support of his motion, O'Neal simultaneously files and relies upon the following:

1. Memorandum of Law;
2. Affidavit of O'Neal attached as Exhibit 1;

3. Affidavit of Debra Schamberg, R.N. attached as Exhibit 2; and
4. Order of the Fifth Circuit Court for Davidson County, Tennessee Denying Motion to Compel Production of Reports and Communications Between St. Thomas Outpatient Neurological Center, LLC and Michael O' Neal attached as Exhibit 3.

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF THE MOTION FOR PROTECTIVE ORDER
FOR MICHAEL O' NEAL

Michael O' Neal has moved this Court for a protective order concerning a subpoena duces tecum issued to him in this matter. The grounds for this motion are: (1) most materials subject of the subpoena duces tecum are privileged and are not discoverable under the Tennessee Patient Safety and Quality Improvement Act ("TPSQIA") codified at Tenn. Code Ann. § 63-1-150 and § 68-11-272; (2) recognition by this Court of a medical peer review privilege for the materials subject of the subpoena duces tecum is consistent with the public policy evident in the TPSQIA, the intent behind the Patient Safety Quality Improvement Act of 2005 ("PSQIA"), and the particular circumstances of this case; (3) discovery of the materials subject of the subpoena duces tecum if allowed by this Court will render ineffective the ruling of the Tennessee court which barred discovery of O'Neal's reports and communications related to his pharmacy consulting for St. Thomas Outpatient Neurological Center, LLC ("STOPNC"), and (4) the subpoena duces tecum at issue is overly broad.

Introduction

The Court's jurisdiction

This multidistrict litigation involves claims for wrongful death and personal injury arising

out of the administration of an injectable steroid, methylprednisolone acetate, manufactured by New England Compounding Pharmacy, Inc. (“NECC”). On motion of NECC’s bankruptcy trustee, this Court assumed jurisdiction over all federal and state court cases against NECC and its affiliates.

Subpoena duces tecum to Michael O’Neal

This motion for protective order seeks to limit a subpoena duces tecum issued to O’Neal by the Plaintiffs’ Steering Committee. The subpoena commands O’ Neal to produce “[a]ll correspondence to, from, or between [him] and/or the St. Thomas Outpatient Neurological Center, LLC [(“STOPNC”)], its employees or agents, related to or mentioning compounding pharmacies and/or compounded pharmaceuticals and all documents related to the New England Compounding Pharmacy; and all documents related to Depo Medrol and/or generic equivalent and/or methylprednisolone acetate.”¹ The request for production covers the period from January 1, 2000 to September 30, 2012.²

Efforts to resolve discovery dispute pursuant to Local Rule 37.1

The undersigned counsel, Stephen W. Elliott, and Benjamin A. Gastel of the Plaintiffs’ Steering Committee conducted a discovery conference via telephone on August 28, 2015. The telephonic conference took about thirty minutes. The parties conferred in good faith to resolve by agreement their dispute concerning the issuance of the subpoena duces tecum to O’ Neal but failed to reach any agreement on the issue.

Facts

¹Subpoena to Michael O’Neal to Testify at a Deposition in a Civil Action dated August 19, 2015.

²*Id.*

O' Neal is a licensed pharmacist in the State of Tennessee.³ Since 2007, he has been working as a pharmacist consultant for STOPNC⁴. STOPNC is a licensed ambulatory surgical treatment center.⁵ As pharmacist consultant, O' Neal performs quality improvement activities related to evaluating the safety, quality, processes and appropriateness of STOPNC's purchase, storage and use of medications.⁶ He also evaluates the safety, quality, processes, and appropriateness of healthcare services at STOPNC.⁷ He conducts monthly inspections at STOPNC to evaluate and improve the quality of the healthcare services rendered at STOPNC.⁸ His duties at these monthly inspections include (1) ensuring that STOPNC operates in compliance with applicable state and federal laws regarding medications; (2) ensuring that STOPNC's staff members are properly carrying out various internal checks regarding STOPNC's medications; (3) evaluating, reviewing, and where necessary, recommending improvements of the methods, procedures and/or treatments being utilized at STOPNC; and (4) reviewing the activities of healthcare providers with regard to the purchase, use and storage of medications.⁹

As part of his activities to evaluate and improve the healthcare services rendered at STOPNC, O'Neal creates reports for STOPNC identifying areas of excellence and those in need of

³Exhibit 1, Affidavit of Michael O'Neal, ¶2.

⁴Exhibit 1, ¶3 and ¶5; Exhibit 2, Affidavit Debra Schamberg, RN, ¶4 and ¶6.

⁵Exhibit 2, ¶3.

⁶Exhibit 1, ¶3; Exhibit 2, ¶6.

⁷Exhibit 1, ¶3; Exhibit 2, ¶12.

⁸Exhibit 1, ¶13; Exhibit 2, ¶13.

⁹Exhibit 1, ¶14-16; Exhibit 2, §14-17.

improvement.¹⁰ He typically submits these reports to STOPNC's personnel Debra Schamberg and Cindy McLendon.¹¹ He works with Schamberg and McLendon to form strategies that will address areas which need improvement or will further improve areas in which STOPNC is operating satisfactorily.¹² The overall goal of this collaboration between O'Neal, Schamberg, and McLendon is to improve the healthcare services at STOPNC¹³.

On or about May 2013, a plaintiff in the Tennessee Court case against STOPNC moved the Court to compel production of the reports and communications between STOPNC and O'Neal¹⁴. The Tennessee Court denied the motion to compel¹⁵. The Tennessee Court found that the reports and communications related to O'Neal's pharmacy consulting for STOPNC are protected from discovery by the TPSQIA.¹⁶

The subpoena duces tecum subject of this motion for protective order is another attempt to discover the same reports and communications between STOPNC and O'Neal. As fully discussed below, these documents are privileged under Tennessee peer review privilege law and are not subject

¹⁰Exhibit 1, ¶18-19; Exhibit 2, ¶18.

¹¹*Id.*

¹²Exhibit 1, ¶20; Exhibit 2, ¶21.

¹³*Id.*

¹⁴ A healthcare liability/wrongful death action docketed as Case No. 13C417 was filed by plaintiff Wayne A. Reed against STOPNC and other defendants at the Circuit Court for Davidson County, Tennessee arising from the death of Diana Reed allegedly caused by infections from steroid injections purchased from NECC.

¹⁵Exhibit 3, Order Denying Motion to Compel Production of Reports and Communications Between STOPNC and O'Neal.

¹⁶*Id.*

to discovery.

Law and Argument

1. Protective Orders

This motion is governed by Fed. R. Civ. P. 26(c)(1) and Fed. R. Civ. P. 45(c)(3). The former relates to protective orders and the latter to quashing and modifying subpoenas. Fed. R. Civ. P. 26(c)(1) provides in pertinent part:

A party or any person from whom discovery is sought may move for a protective order in the court where the action is pending... The court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including... (A) forbidding the disclosure or discovery; (B) specifying terms, including time and place for the disclosure or discovery...(D) forbidding inquiry into certain matters, or limiting the scope of disclosure or discovery to certain matter.

Fed. R. Civ. P. 45(c)(3), on the other hand, states:

On timely motion, the court for the district court where compliance is required must quash or modify a subpoena that... (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies.

2. Tennessee peer review privilege law is the applicable law in this matter.

The starting point for evaluating assertions of privilege in federal cases is Rule 501 of the Federal Rules of Evidence. Rule 501 provides:

The common law - as interpreted by United States courts in the light of reason and experience- governs a claim of privilege unless any of the following provides otherwise:

- the United States Constitution;
- a federal statute; or
- rules prescribed by the Supreme Court.

But in a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision.¹⁷

¹⁷Fed.R. Evid. 501 (underscoring supplied).

The second sentence of Rule 501 provides for the determination of privilege questions in accordance with state law in civil actions and proceedings with respect to a claim or defense as to which state law supplies the rule of decision. If an item of proof tends to support or defeat a claim or defense or an element of a claim or defense and if state law supplies the rule of decision for that claim or defense, state privilege law applies to that item of proof.¹⁸ Where state and federal claims are joined but the evidence sought to be excluded affects only the state claims, the state law of privilege applies.¹⁹

In *Jaffee v. Redmond*, 518 U.S.1, 116 S.Ct. 1923, 135 L.Ed.2d 337 (1996), the United States Supreme Court recognized that state privileges apply in federal cases involving only state claims.²⁰ In *Jaffee*, a case involving alleged civil rights violations (federal claims), the Supreme Court chose to recognize a federal psychotherapist-patient privilege²¹. The defendants argued that either (1) Illinois' statutory psychotherapist-patient privilege should apply or (2) the Court should adopt a federal psychotherapist-physician privilege. The Supreme Court recognized in a footnote that "if only a state law claim had been asserted in federal court, the second sentence in Rule 501 would have extended [Illinois's statutory psychotherapist-patient privilege] to that proceeding."²²

Tennessee law supplies the rule of decision in this matter. Thus far, all claims pending in

¹⁸Conference Committee Report No. 93-1597 (1974), p. 7.

¹⁹*Shaklee Corp. v. Gunnell*, 110 F.R.D.190, 20 Fed.R. Evid. Serv. 3d 460 (N.D. Cal. 1986).

²⁰*Jaffee*, 518 U.S. 14, 116 S.Ct. 1923, n. 15

²¹*Id.* at 15.

²²*Id.* at 14 n. 15.

the Tennessee Courts against NECC have all been state tort claims. Pursuant to Rule 501, state privilege law applies in this matter.

Furthermore, it appears to counsel that all bankruptcy-related matters have been resolved. Accordingly, should this matter be remanded to the appropriate courts of original jurisdiction for additional discovery and trial (because there is no longer any federal jurisdiction), Tennessee law would obviously apply in Tennessee courts.

That Tennessee privilege law, particularly Tennessee peer review privilege law, should apply in this matter where only state law claims have been asserted finds support in the decisions of the federal courts of appeals which have addressed this issue. The Third, Tenth, and Eleventh Circuits have held that state peer review privilege law applied in medical malpractice diversity cases that do not involve any federal questions, like the Tennessee cases involved in this matter.²³ At least one district court has held that a state peer review privilege applied in a medical malpractice diversity case.²⁴

Additionally, several district courts have held that a state's peer review privilege applies where both federal and state claims were present but the peer review material was irrelevant to the federal claims.²⁵

²³ See e.g. *Samuelson v. Susen*, 576 F.2d 546 (3d Cir. 1978); *Nalder v West Park Hosp.*, 254 F.3d 1168 (10th Cir. 2001); *Somer v. Johnson*, 740 F.2d 1473 (11th Cir. 1983).

²⁴ See *Burnett v. Ghassem*, 685 F.Supp. 430 (D. Del. 1988).

²⁵ *Freeman v. Fairman*, 917 F.Supp. 586 (N.D. Ill. 1996)(holding that Illinois peer review statute applied in malpractice case with additional § 1983 claim because peer review materials had minimal probative value for § 1983 claim); *Bennett v. Kent Count Mem. Hosp.*, 623 F.Supp.2d 246 (D. Rhode Island 2009)(holding that peer review privilege applied in medical malpractice case with EMTALA claim where peer review material was irrelevant to EMTALA claim); *Veith v. Portage County*, No. 5:11CV2542 (N.D. Ohio October 11, 2012 (not reported))

Because only state tort claims have been asserted against NECC in the Tennessee cases and because the evidence sought to be excluded in this motion affects only these state law claims, Tennessee peer review privilege law applies to this motion for protective order.

3. O' Neal's reports and communications to STOPNC are not discoverable under the TPSQIA.

Under the TPSQIA, "the records of a QIC [Quality Improvement Committee]²⁶ and testimony or statements by a healthcare organization's officers, directors, trustees, healthcare providers, administrative staff, employees or other committee members or attendees relating to the activities of the QIC shall be confidential and privileged and shall be protected from direct or indirect means of discovery, subpoena or admission into evidence in any judicial or administrative proceeding."²⁷

In determining whether the privilege under the TPSQIA applies, the threshold issue to be determined is whether O' Neal functioned as a QIC under the statute. O' Neal must meet three requirements to be considered a QIC under the statute:

1. He must fit into one of three categories of a QIC;
2. He must serve one of the five enumerated purposes of a QIC; and
3. He must be performing a function in furtherance of one of those five purposes.²⁸

Each of these requirements is explained below.

(holding that Ohio peer privilege applied in medical malpractice with additional § 1983 claim sounding in malpractice).

²⁶ A QIC is TPSQIA's equivalent to a peer review committee.

²⁷T.C.A. § 68-11-272(c)(1).

²⁸T.C.A. § 68-11-272(b)(4)(underscoring supplied).

A. O'Neal is a QIC.

A QIC under the statute may be any of the following: (1) a committee formed or retained by a healthcare organization; (2) an activity of a healthcare organization; or (3) one or more individuals employed by a healthcare organization to perform one of the enumerated functions.²⁹

O'Neal was employed and retained by STOPNC as a pharmacist consultant to to evaluate the safety, quality, processes, and appropriateness of healthcare services at STOPNC, including the safety, quality, processes and appropriateness of STOPNC's purchase, storage and use of medications. Under the statute's definition, O' Neal is a QIC.

B. O'Neal serves several of the enumerated purposes of a QIC under the statute.

The TPSQIA requires that the QIC perform a function for one of the following five purposes: to evaluate the (1) safety, (2) quality, (3) processes, (4) costs, and (5) appropriateness or necessity of healthcare services.³⁰

O' Neal's responsibilities as pharmacist consultant for STOPNC serve all of the enumerated purposes of a QIC under the statute. As pharmacist consultant, O'Neal conducts monthly inspections at STOPNC to evaluate and improve the quality of the healthcare services rendered at STOPNC. His duties at these monthly inspections include: (1) ensuring that STOPNC operates in compliance with applicable state and federal laws regarding medications; (2) ensuring that STOPNC's staff members are properly carrying out various internal checks regarding STOPNC's medications; (3) evaluating, reviewing, and, where necessary, recommending improvements of the methods, procedures, and/or treatments being utilized at STOPNC; and (4) reviewing the activities of

²⁹*Id.*

³⁰*Id.*

healthcare providers with regard to the purchase, use and storage of medications. Clearly, O'Neal serves the purposes of a QIC under the statute.

C. O'Neal performs several of the specifically enumerated functions of a QIC.

The TPSQIA provides a non-exhaustive list of functions to illustrate the purposes and roles of a QIC protected by the statute.³¹ O'Neal performs most of these functions, specifically:

(A) Evaluation and improvement of the quality of healthcare services rendered;

(L) Evaluation, review or improvement of methods, procedures or treatments being utilized;

(O) Activities to determine healthcare organization's compliance with state and federal regulations.³²

O'Neal's responsibilities as a pharmacist consultant for STOPNC are consistent with the enumerated functions of a QIC. Therefore, he is a QIC under the statute.

D. Because O'Neal qualifies as a QIC under the statute, his records and communications as a QIC are privileged and protected from discovery.

The TPSQIA defines the records of a QIC as follows:

[R]ecords of interviews, and all reports, incident reports, statements, minutes, memoranda, charts, statistics, evaluations, critiques, test results, corrective actions, disciplinary actions, and any and all other documentation generated in connection with the activities of a QIC and any patient safety work product as defined at § 921 of the Patient Safety and Quality Improvement Act of 2005, P.L. 109-41, as amended.³³

³¹*Id.* § 68-11-272(b)(4)(A)-(P).

³²*Id.*

³³*Id.* §68-11-272(b)(5)(underscoring supplied).

By its plain language, the TPSQIA protects from “direct or indirect means of discovery, subpoena or admission into evidence in any judicial... proceeding any records of a QIC.”³⁴ Therefore, O’Neal’s reports, statements, memoranda, charts, evaluations, and any and all other documentation generated in connection with his activities as a QIC for STOPNC are protected from discovery. Pursuant to the TPSQIA, this Court should grant this motion for a protective order and limit the subpoena duces tecum issued to O’Neal by Plaintiffs’ Steering Committee.

4. Recognition by this Court of a medical peer review privilege for the confidential documents generated by O’Neal in his capacity as a pharmacist consultant for STOPNC would be consistent with the public policy evident in the TPSQIA, the intent behind PSQIA, and the particular circumstances of this case.

Rule 501 of the Federal Rules of Evidence provides that “[t]he common law - as interpreted by United States courts in the light of reason and experience- governs a claim of privilege” in federal cases.³⁵ In *Jaffee*, the United States Supreme Court interpreted Rule 501’s “reason and experience” phrase to mean that federal law will recognize a privilege that “ ‘promotes sufficiently important interests to outweigh the need for probative evidence....’ ”³⁶ In this regard, the Court observed that policy decisions of the States bear on the question whether federal courts should recognize a new privilege or amend the coverage of an existing one.³⁷ After all, “state legislatures are fully aware of the need to protect the integrity of the factfinding functions of their courts and a State’s promise of confidentiality would have little value if the [person it protects] were aware that the privilege would

³⁴*Id.* §68-11-272(c)(1)

³⁵Fed.R.Evid. 501.

³⁶*Jaffee*. 518 U.S., 9-10, 116 S.Ct. 1923.

³⁷*Id.* at 12-13, 116 S.Ct. 1923.

not be honored in a federal court.”³⁸ This consideration is at the very heart of this motion.

In this case, recognition by this Court of a medical peer review privilege for the confidential documents generated by O’Neal in his capacity as pharmacy consultant for STOPNC would be consistent with the public policy behind the TPSQIA and the PSQIA.

1. The TPSQIA

The TPSQIA states that it is the “policy of [Tennessee] to encourage the improvement of patient safety, the quality of patient care and the evaluation of the quality, safety, costs, processes and necessity of healthcare services by hospitals, healthcare facilities and healthcare providers.”³⁹ To this end, “Tennessee recognizes that certain protections must be available to these entities to ensure that they are able to effectively pursue these measures.”⁴⁰ Pursuant to this policy, the TPSQIA protects from discovery any records of a QIC as well as any statements by a healthcare organization’s officers, directors, trustees, staff, or employees relating to the activities of the QIC.⁴¹

2. The PSQIA

In 2005, Congress enacted the PSQIA⁴². The PSQIA “announces a more general approval for the medical peer review process and more sweeping evidentiary protections for materials used therein.”⁴³ The PSQIA was designed to encourage a “culture of safety” by “providing for broad

³⁸*Id.* at 13, S.Ct. 1923.

³⁹T.C.A. § 68-11-272(a).

⁴⁰*Id.*

⁴¹*Id.* § 68-11-272(c)(1).

⁴²42 U.S.C. §299b-21 *et seq.*

⁴³*K.D. ex rel. Dieffenbach v. U.S.*, 715 F.Supp.2d 587, 595 (D.Del. 2010).

confidentiality and legal protections of information collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety.”⁴⁴ Specifically, the PSQIA creates a privilege for any “data, reports, records, memoranda, analyses, or written or oral statements” that a healthcare provider assembles or develops and reports to a patient safety organization (“PSO”) on a timely basis.⁴⁵ Congress intended the broad protection afforded by the PSQIA to complement, not supplant, existing law providing greater privilege.⁴⁶

Since the enactment of the PSQIA, a number of federal courts have recognized some form of medical peer review privilege under federal common law.⁴⁷ In doing so, “these courts have examined the legislative history of the PSQIA and construed it as “signaling a shift in congressional policy aimed at providing broad protection for peer review work product in an effort to improve patient safety and quality of care.”⁴⁸

More recently, Massachusetts district court Judge Sorokin recognized a medical peer review privilege under the federal common law in *Tep v. Southcoast Hospitals Group, Inc.*, No. 13-11887, 2014 WL 6873137 (D. Massachusetts, Dec. 4, 2014). In *Tep*, the plaintiff sought discovery of documents concerning the hospital’s internal investigation of the decedent’s medical care at the hospital. The Massachusetts district court barred the discovery. The district court relied on the

⁴⁴S.Rep. No. 108-196, at *3 (2003).

⁴⁵42 U.S.C. §§ 299b-21(7) and 299b-22(a).

⁴⁶42 U.S.C. § 299b-22(g).

⁴⁷*See Sevilla v. United States*, 825 F.Supp.2d 1057, 1068-69 (N.D. Ill. 2012); *Francis v. U.S.*, 2011 WL 2224509, at *7 (S.D.N.Y., May 31, 2011); *Dieffenbach*, 715 F.Supp.2d at 592.

⁴⁸*See Dieffenbach*, 715 F.Supp.2d at 596.

privilege created by the PSQIA to support the creation of a federal common law privilege applicable to the case. As explained by the district court:

Although the privilege created in the PSQIA does not apply directly, it supports creation of a federal common law privilege applicable to this action. The documents at issue are like the “patient safety work product” protected under the PSQIA, and they were generated during reviews and analyses that are tantamount to a “patient safety evaluation system” under the PSQIA. Had they been provided to a “patient safety organization” listed in the PSQIA, it appears they would be statutorily privileged. In light of that, “protecting otherwise confidential and evaluative materials resulting from this process would not substantially offend the federal policy announced in the PSQIA.”⁴⁹

Similar to *Tep*, recognition of a federal common law medical peer review privilege as regards the documents generated by O’Neal in his role as pharmacy consultant for STOPNC would be consistent with the policy behind the TPSQIA and the PSQIA of promoting peer review to improve quality of health care services and patient safety. Recognizing a medical peer review privilege in this matter furthers the state and national interest in the protection of the health of the citizenry and does no more than require the Plaintiffs’ Steering Committee to prove its case with evidence unconnected to the peer review materials. In contrast to the significant public and private interests supporting recognition of the privilege, the likely evidentiary benefit that would result from the denial of the privilege is modest.⁵⁰ “Not recognizing the privilege would inhibit the candor that is essential to effective peer review, and thus frustrate the achievement of what is undisputably a national interest of overarching significance.”⁵¹ This Court should grant the motion for protective

⁴⁹*Tep v. Southcoast Hospitals Group, Inc.*, No. 13-11887, 2014 WL 6873137, at *6 (D. Massachusetts, Dec. 4, 2014).

⁵⁰*Jaffee*, 518 U.S. at 11-12, 116 S.Ct. 1923.

⁵¹*Sevilla*, 852 F.Supp.2d at 1061.

order for the subpoena issued to O'Neal.

5. The discovery of the materials subject of the subpoena duces tecum if allowed by this Court will render ineffective the ruling of the Tennessee court which barred discovery of O'Neal's reports and communications related to his pharmacy consulting for STOPNC.

A Tennessee Court has already ruled that O'Neal's reports and communications related to his pharmacy consulting for STOPNC are protected from discovery under the state's peer review privilege law.⁵² A contrary ruling by this Court allowing discovery of these same peer review materials would render ineffective the Tennessee court's ruling on this issue. Given the apparent fact that all federal issues have been resolved, these cases should be remanded for the completion of discovery and for trial. Discovery of these peer review materials if allowed by this Court would let the genie out of the bottle, and there is no way that the genie could be put back in, even if a Tennessee court after remand were disposed to do so.

6. The subpoena duces tecum at issue is overly broad, and therefore, unduly burdensome on O'Neal.

A subpoena issued to a non-party pursuant to Rule 45 is subject to the relevancy requirement of Rule 26 of the Federal Rules of Civil Procedure.⁵³ Although relevance is generously construed, the party from whom discovery is sought may move for a protective order, and the court may issue an order to protect the movant from annoyance, embarrassment, oppression, or undue burden or expense for good cause.⁵⁴ The undue burden category encompasses situations where the subpoena

⁵²Exhibit 3.

⁵³*E.E.O.C. v. Texas Roadhouse, Inc.*, 303 F.R.D.1, 2 (D.Massachusetts 2014).

⁵⁴*Id.*

seeks irrelevant information or where the subpoena at issue is overbroad.⁵⁵

The subpoena duces tecum issued to O'Neal seeks "all documents related to [NECC]" and "all documents related to Depo Medrol and/or a generic equivalent and/or methylprednisolone acetate" for the period January 1, 2000 to September 30, 2012. This language of the subpoena duces tecum conceivably covers all data, publications, studies, and/or research materials of O'Neal related to NECC, Depo Medrol, its generic equivalent and methylprednisolone acetate. The subpoena to O'Neal is sweeping and indiscriminate. It requires the production of materials or documents that are extraneous to O'Neal's pharmacy consulting work with STOPNC and are completely unrelated to any possible issue in this case. Additionally, it bears stressing that O'Neal's pharmacy consulting work with STOPNC only started in 2007.⁵⁶ The subpoena seeks documents beginning on January 1, 2000. There is no reasonable basis why O'Neal should be made to produce materials from January 1, 2000 when he has not even working with STOPNC at that time. Because the subpoena at issue is overly broad, and therefore, unduly burdensome on O'Neal, this Court must grant a motion for protective order and limit the subpoena issued to O'Neal.

Conclusion

For the foregoing reasons, Michael O'Neal respectfully requests that this Court grant his motion for protective order by (1) barring discovery of the materials subject of the subpoena and (2) disallowing any testimony of O' Neal about these same materials.

⁵⁵*Singletary v. Sterling Transport, Inc.*, 289 F.R.D. 237, 240 (E.D. Va. 2012).

⁵⁶Exhibit 1, ¶3 and ¶5; Exhibit 2, ¶4 and ¶6.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that the foregoing document was filed electronically through the CM/ECF system on December 4, 2015, and served electronically on all counsel of record.

/s/ Kathryn M.A. Young

Kathryn Young